# EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON PAIN, FUNCTIONALITY AND CAPSULAR THICKNESS IN INDIVIDUALS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS

SHORT SYNOPSIS

*Submitted in partial fulfilment of the requirement of the degree of*

DOCTOR OF PHILOSOPHY

to

*Manav Rachna International Institute of Research & Studies*

*(Deemed to be university)*

*by*

**SHEENA ARORA**

Registration number: 19/PhD/009

Under the supervision of

Supervisor

**Prof. (Dr.) Moattar Raza Rizvi**

**Dean, School of Allied Health Sciences**

**MRIIRS**

Joint Supervisor

**Dr. Khyatee**

**Director and Co-Founder**

**Pratyaksh Medical Care, Delhi**

SCHOOL OF ALLIED HEALTH SCIENCES

MANAV RACHNA INTERNATIONAL INSTITUTE OF RESEARCH & STUDIES

SECTOR-43, SURAJKUND –DELHI ROAD, FARIDABAD – 121001

**Certificate**

I hereby declare that the short synopsis "EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON PAIN, FUNCTIONALITY AND CAPSULAR THICKNESS IN INDIVIDUALS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Physiotherapy under faculty of Allied Health Sciences of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2019. It is a bona fide record of original work carried out under the joint supervision of Prof. (Dr.) Khyatee and has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

(SHEENA ARORA)
19/Ph.D /009

Prof. (Dr) Moattar Raza Rizvi
(Supervisor)
Dean, School of Allied Health Sciences.

Prof. (Dr.) Khyatee
(Joint Supervisor)
Director and Cofounder,
Pratyakash Medical Care

**(Chairman, DRC)**

**Chairperson, CDP**

## ABSTRACT

**Background**: Adhesive Capsulitis is a challenging condition marked by pain and limited active and passive range of motion (ROM) of shoulder. Diabetic patients are more prone to develop chronic inflammation and proliferative fibrosis. Physical therapy is the primary form of treatment provided for this condition. Within the realm of shoulder pain assessment and management, the McKenzie Method/ Mechanical diagnosis and treatment (MDT) is an area that has received relatively less exploration, particularly in individuals with diabetes.

**Objectives**: This study aims to find out the efficacy of McKenzie (Mechanical Diagnosis and Treatment) method on functionality and capsular thickness in patients with Stage 2 Diabetic Adhesive Capsulitis.

**Methodology**: It will be an RCT with 4 parallel groups (2 intervention and 2 control group). A total of 92 participants will be selected as per inclusion and exclusion criteria and categorized into groups i.e., 2 groups (Group A1 and A2) with controlled diabetes and 2 groups with uncontrolled diabetes (Group B1 and B2). Group A1 (Controlled Diabetes) will be advised to follow home exercise program with conventional treatment and shall be taken as control for Group A2 (Controlled Diabetes) receiving treatment according to MDT. Similarly, Group B1 (Uncontrolled Diabetes) will be given conventional treatment for adhesive capsulitis with home exercise and shall be serving as control for B2 (Uncontrolled Diabetes) receiving the MDT. Outcome variables will be measured at baseline (pre assessment) and post treatment at 2 weeks. After completing the treatment, the subjects would be given a home exercise program as prophylaxis, and they shall be followed-up at 6 weeks and 10 weeks and will be again assessed for outcome variables.

**Expected outcome:** MDT is expected to be valuable tool for diagnosis and treatment for stage 2 diabetic adhesive capsulitis



**Keywords**: Adhesive capsulitis, Diabetes, McKenzie Method, Mechanical Diagnosis and Therapy (MDT).

## CONTENTS


| S. No. | DESCRIPTION | PAGE NO. |
|---|---|---|
| 1. | Introduction | 1-4 |
| 2. | Literature Review | 5-7 |
| 3. | Problem statement and research gap | 8-9 |
| 4. | Description of broad area | 10 |
| 5. | Research Objectives | 11 |
| 6. | Research Methodology | 12-17 |
| 7. | Expected outcome | 18 |
| 8. | References | 19-22 |
| 9. | Appendices | 23-26 |

# INTRODUCTION

## Definition, clinical course and risk factors of adhesive capsulitis

Adhesive Capsulitis (AC) is an incapacitating condition marked by painful limitations in both active and passive shoulder range of motion (ROM). This phenomenon was initially described by Duplay in 1872 as "scapulohumeral periarthritis." Following that, in 1934, Codman coined the term "frozen shoulder" to describe the identical condition, a terminology that persists in current usage (Codman,1934). Neviaser (1945) expanded upon this concept by incorporating the thickening of the glenohumeral joint capsule, introducing the term "adhesive capsulitis". This updated expression better captures the pathological changes associated with the condition, emphasizing the adhesive nature of the thickened joint capsule. Presently, "Adhesive capsulitis" is characterized as a painful syndrome marked by a gradual reduction in both active and passive ranges of motion in shoulder movements. This condition arises from progressive fibrosis, culminating in the contracture of the glenohumeral joint. (Codman,1934; Neviaser, 1945).

The progression and clinical course of Adhesive Capsulitis can be divided into four stages. The first painful stage involves gradually increasing pain referred to lateral shoulder and restricted ROM that lasts upto 3 months. This phase is commonly accompanied by Muscle spasms in the trapezius. The second stage, involves night pain with stiffness increasing in capsular pattern i.e. flexion, abduction, Internal and external rotation. This stage lasts for next four to six months. The third stage is characterized by a progressive loss of movement at shoulder, with movement continuing to be limited by pain accompanied by marked stiffness. The final stage, involves a gradual return of motion, with spontaneous reduction in pain and recovery of partial or complete ROM over years. Symptoms of adhesive capsulitis may manifest in either one or both shoulders, and the condition tends to be more prevalent among individuals aged 40-60 years. It occurs with greater frequency in women and those with diabetes. In this condition, the connective tissue enveloping the shoulder joint undergoes inflammation and stiffness. The hypercellular, collagenous tissue, characterized by a thin synovial layer, exhibits similarities to other fibrosing conditions. This process leads to the formation of tight bands known as adhesions, resulting in both pain and constrained motion (Neviaser & Hannafin, 2010).

Risk factors for AC include aging, diabetes (Massoud S. N. et. al., 2002; Ogilvie-Harris, D. J., & Myerthall, S. 1997), Hypothyroidism, Parkinson’s disease, and various Heart conditions. (Wohlgethan, J. R. 1987; Bowman, C. A, 1988) About 2-5% of the population suffer from AC

of which majority patients are female. (Ewald A, 2011) Adhesive capsulitis occurs in ages ranging from 4th decade to 6th decade of life and the non-dominant hand is more frequently involved. (Wong PLK, 2010) Contralateral extremity is involved in about 20% to 30% of those affected by the condition with causes remaining unclear (Zuckerman, J. D., & Rokito, A, 2011).

**Diabetes and Adhesive Capsulitis**

This condition is more likely to develop in diabetics by almost 13%, that is five times greater than non-diabetics. Diabetes mellitus has also been observed in 30% of individuals with adhesive capsulitis. (Zreik et al., 2016) As it is known that diabetes delays the healing process, it is very critical for the therapist to strike a fine balance between treating pain and increasing range of motion. As per the American Diabetes Association, diabetes is categorized as controlled when the HbA1c level is less than 7%, and it is considered uncontrolled if the HbA1c level is equal to or greater than 7% (Adams et al., 2013).

Cagliero et al found musculoskeletal diseases to be more prevalent in diabetic patients i.e., 36% versus 9% in control group (Cagliero et al., 2002). Most of these were dependent on glycemic control and the duration of diabetes. Arkkila and Gautier also found that in individuals with shoulder or hand problems, mean HgA1c levels were higher along with poor glycemic control (Arkkila & Gautier, 2003). The association of diabetes has been well established with adhesive capsulitis (AC). These studies also show the occurrence of AC in type 1 and type 2 diabetics with type 2 being more affected (Tighe & Oakley, 2008). Observationally, there is a tendency for the non-dominant shoulder to be more frequently affected, although the dominant shoulder has been noted to be involved in up to 30% of cases.

Growth factors such as TGF-β are proposed to be involved in development of fibrotic cascade due to stimulation of synovitis (Watson et. al., 2010; Rodeo et. al., 1997).

**Clinical diagnosis of adhesive capsulitis**

The clinical diagnosis of adhesive capsulitis is established through the identification of a gradual onset of shoulder pain, accompanied by stiffness and a progressive reduction in the range of motion at the shoulder joint. This limitation typically initiates with restrictions in external rotation, followed by constraints in abduction and forward flexion. Differential diagnoses for adhesive capsulitis encompass conditions such as calcific periarthritis, rotator cuff impingement, and capsular inflammation associated with osteoarthrosis or inflammatory arthritis (Hannafin & Chaiaia, 2000).

MRI functions as a diagnostic tool for adhesive capsulitis, with indications of the condition manifesting as the thickening of the Coracohumeral Ligament (CHL) and the rotator interval capsule. According to Mengiardi et al., their study highlights that a CHL thickness of ≥ 4 mm exhibited a specificity of 95% and sensitivity of 59%, while a thickness of ≥ 7 mm in the rotator interval capsule displayed a specificity of 86% and sensitivity of 64% in detecting adhesive capsulitis. (Mengiardi et. al., 2004) These findings underscore the utility of MRI in assessing specific anatomical changes associated with adhesive capsulitis and contribute valuable metrics for diagnostic accuracy (Sofka et. al., 2008).

**Management of Adhesive capsulitis**

The symptoms can be managed with, oral or intra-articular corticosteroids, physiotherapy, acupuncture, arthroscopic capsular release, hydrodilatation and manipulation under anesthesia. However, the most accurate treatment for adhesive capsulitis is still uncertain, and the management of this condition typically involves a multimodal approach (Fields et al., 2019; Redler & Dennis, 2019).

The management of adhesive capsulitis typically adopts a multimodal approach, encompassing physical therapy, nonsteroidal anti-inflammatory drugs, intra-articular corticosteroid injections, and, in certain instances, manipulation under anesthesia (MUA) for patients who do not respond to conservative treatments (Page, 2010). However, the efficacy of these interventions in individuals with stage 2 diabetic adhesive capsulitis remains a subject of interest and investigation. Stage 2 adhesive capsulitis is characterized by increasing pain and stiffness, significantly affecting shoulder function and mobility. Stage 2 adhesive capsulitis is marked by escalating pain and stiffness, leading to a substantial impact on shoulder function and mobility. Many of the studies show temporary reduction in symptoms with a relapse within 3-6 weeks with minimal or no improvement in ROM (Kelly et. al., 2013).

Nonsurgical treatments are the first option for most patients with adhesive capsulitis, and more than 90% of patients respond to conservative interventions to control pain and restore motion. Physiotherapy has been extensively used to treat AC, despite a paucity of high-level studies stating its benefit over observation or pharmacological treatment alone (Nakandala et al., 2021). Many different approaches like mobilization with movement, or Maitland mobilization along with gentle stretching along with active ROM exercises are used to treat the condition. A systematic review done in 2015 found fair evidence that manual mobilization along with exercise provided an increased ROM and functionality in persons with adhesive capsulitis

(Ramirez J., 2019). Results of Physiotherapy has also been compared to that of intra-articular corticosteroid injections, with varying results. Extracorporeal shockwave therapy (ESWT) is also among one of the promising therapy for adhesive capsulitis (Chen et al., 2014). The recovery process for adhesive capsulitis can be a long process of which patients should be made aware.

**Mechanical Diagnosis and Therapy**

The "McKenzie method of Mechanical Diagnosis and Therapy (MDT)" proposed by Robin McKenzie is known well and commonly used in managing spinal disorders. (McKenzie 1981, 1990; McKenzie and May 2000, 2003). This system uses repeated movement testing for mechanical evaluation of the condition. In this repeated movements are performed in different planes while monitoring the symptoms and mechanical response to determine the condition and its treatment. According to McKenzie, the mechanical classification for extremities (such as adhesive capsulitis) are as follows:

- **"Derangement syndrome:** identified by a rapid response to a direction-specific loading strategy, known as the directional preference. A lasting improvement in symptoms, range of motion, and enhanced function will be achieved once the directional preference has been established and utilized.
- **Articular dysfunction:** distinguished by intermittent and consistent pain only produced at a diminished end range with a slower response to specific tissue loading strategy.
- **Contractile dysfunction:** distinguished by intermittent pain consistently produced, but this time only when the Musculotendinous unit is loaded, for instance, with an isometric contraction against resistance.
- **Postural syndrome:** intermittent pain only produced by prolonged postures that, once avoided, result in a return to a normal pain-free state. The remainder of the physical examination is normal."

There were case studies which showed that MDT changes in range of motion, pain and function in the shoulder pain (Remsburg J, 2019 and Bowser & Swanson, 2016). Another randomized clinical trial with MDT intervention showed improvement for shoulder pain and upper extremity function (Haider Abady et al., 2017). With best of our knowledge only a single study which showed changes in the pain, range of motion and function score of shoulder in patients with Stage II AC (Metgud et.al., 2017).

## LITERATURE REVIEW

### Conventional Treatment for Adhesive Capsulitis

- **Mueller M. et.al.** (2018) In a randomized controlled clinical trial with a prospective design, involving fifty-two participants diagnosed with type II diabetes and experiencing either shoulder pain or limited shoulder motion, the ShoMo (Shoulder Movement Intervention) group underwent a progressive and active shoulder movement program. Simultaneously, the wellness group received training aimed at managing diabetes. Outcome measures, such as the range of motion (ROM) during active shoulder flexion, and the Shoulder Pain and Disability Index (SPADI), were employed. Post-intervention, the ShoMo group exhibited a 7.2-degree higher active shoulder flexion compared to the wellness group, although this improvement showed inconsistency in successive follow-ups. Following the intervention, the SPADI score for the ShoMo group remained consistently higher by 12.7 points compared to the wellness group, and this discrepancy persisted for a period of nine months. These findings suggest the potential efficacy of the Shoulder Movement Intervention in enhancing shoulder flexibility in individuals with type II diabetes and shoulder issues, although long-term effects on SPADI scores warrant consideration. (Mueller, Sorensen, McGill, Clark, Lang, Chen, Bohnert & Hastings, 2018).
- **Neviaser A. et.al** (2011) published that as a result of contracture and fibrosis of the capsule of the joint, AC is characterized by a painful, progressive loss of active and passive shoulder ROM. However, other shoulder pathologies can result in a similar clinical presentation and need to be considered. Determining the aetiology is crucial because treatment is focused on the underlying cause of the symptoms being experienced. The history and physical examination can provide subtle hints that can help distinguish AC from other illnesses that result in pain and stiffness in shoulder. It is debatable how adhesive capsulitis develops naturally. Gentle, progressive stretching exercises are the first line of treatment for genuine adhesive capsulitis, or capsular limitation of motion. With nonsurgical treatment, the majority of patients get well. Surgery indications ought to be tailored to the individual. The standard recommendation for surgery is failure to achieve any improvement in symptoms and continued functional impairment even after 6 months of physiotherapy. Adhesive

capsulitis must be treated postoperatively carefully to maintain motion in order to reduce recurrence. (Neviaser & Neviaser, 2011).

- **Tanaka K. et.al** (2010) conducted a randomized control trail with 120 patients suffering from adhesive capsulitis. The functional outcomes measured consisted of two parameters: the time (T) taken to reach the plateau point in range of motion and the improved angle of the shoulder joint. ("IA: defined as the value obtained by subtracting the affected shoulder joint angle at baseline from the angle of the ROM plateau point"). The following factors were compared between IA and T: (1) gender, (2) age, (3) handedness, (4) time duration prior to receiving rehabilitation, (5) number of physical therapy sessions received in the hospital setting for joint mobilization, and (6) compliance of home program. The findings suggested that compliance at home and early intervention are more crucial for successful management than the number of physical therapy sessions received. (Tanaka, Saura, Takahashi, Hiura & Hashimoto, 2010)

**McKenzie or Mechanical Diagnosis and Treatment**

- In a case study conducted by **Remsburg J (2019)**, a 59-year-old female diagnosed with multiple hereditary exostoses (MHE) underwent various interventions. These included thoracic manipulation, Mechanical Diagnosis and Therapy (MDT) - McKenzie, and instrument-assisted soft-tissue mobilization over the right shoulder. Range of motion, Numerical pain rating scale and functions of arm and shoulder (Disabilities of Arm, Shoulder Hand score) were used as outcome measures. She reported no pain or limitation in range of motion after 5 visits within 2 weeks. During examination it was found that the ROM of right shoulder was pain-free and as good as the left shoulder. Her DASH score was found to be 0% in a follow-up phone call made 2 weeks later. (Remsburg, 2019)
- A Pre-post experimental study was conducted by **Metgud S. et.al** (2017) with 20 people, both male and female, with a clinical diagnosis of stage II AC, between the ages of 40 and 60. Outcome measures for the administered MDT included the Numerical Pain Rating Scale, shoulder range of motion (ROM), and the Penn Shoulder Score. The study's findings revealed statistically significant alterations in pain, shoulder ROM, and functions of shoulder. (Metgud, Naik & Heggannavar, 2017).
- **Haider Abady A. et.al** (2017), conducted a randomized control trial on 105 individuals. The inclusion criteria age > 18, English speakers, and shoulder pain. MDT

was used for diagnosis and treatment. The outcome measures used were the UEFI and NPRS. Groups Derangement and Spinal classifications scored considerably lower on the NPRS at weeks two and four ($p < 0.05$) than the Dysfunction group. At weeks 2 and 4, the UEFI scores for the Spinal and Derangement classifications exhibited a significant increase compared to those for the Dysfunction group ($p < 0.05$). (Abady, Rosedale, Chesworth, Rotondi & Overend, 2017)

- **Bowser A. et.al** (2016) did a Case Study on a female who was 52 years in age with subacute onset of left shoulder pain. MDT was utilized for diagnosis and intervention. The outcome measurements were shoulder range of motion, the UEFI score, and the VAS. Within six visits spread over eight weeks, the individual showed considerable improvements in the VAS (0-2/10), ROM and UEFI (66/80). (Bowser & Swanson, 2016).

**MRI changes to study coracohumeral ligament and/or capsular thickness**

- **Choi Y. et.al** (2020) conducted a retrospective study involving 29 patients with early adhesive capsulitis (AC) of the shoulder. The study aimed to explore potential correlations between clinical features and MRI findings. Various measurements were taken from MRI images, including maximal axillary capsular thickness, humeral and glenoid capsular thickness in the axillary recess, coracohumeral ligament thickness, and anterior capsular thickness, to investigate any associations between symptoms and MRI findings. It was concluded that MRI can be a useful tool for evaluation of AC and duration of symptoms and limited ROM can be correlated with hyperintensity and thickening of the joint capsule in the axillary recess. (Choi & Kim, 2020)
- **Fields B. et.al** (2019) conducted a literature review, which suggests that diagnosis of AC may be done by MRI imaging. The thickening of the rotator interval joint capsule, coracohumeral ligament, and axillary pouch demonstrates very high specificity and good sensitivity. Conversely, the destruction of the subcoracoid fat triangle exhibits the highest specificity but poor sensitivity. In fat suppressed images, post-contrast enhancement and T2 signal hyperintensity of the inferior glenohumeral ligament show extremely high sensitivity and specificity. Ultrasonography reveals similar findings. Intra-articular injections that are image guided can help to alleviate the symptoms. (Fields, Skalski, Patel, White, Tomasian, Gross, & Matcuk, 2019)

## RESEARCH GAP & PROBLEM STATEMENT

### Research Gap

This study is going to find out the effect of MDT for examination and intervention in subjects with diabetic adhesive capsulitis. This study holds significant promise in advancing our understanding and treatment approaches for individuals grappling with stage 2 diabetic adhesive capsulitis, a musculoskeletal disorder known for its debilitating impact on pain and range of motion. Adhesive capsulitis, particularly prevalent in those with diabetes mellitus, adversely affects daily activities such as sleeping, dressing, and cooking. While physical therapy is a cornerstone of non-invasive treatments for adhesive capsulitis, there is a notable research gap concerning the effects of Mechanical Diagnosis and Treatment (MDT) on diabetic adhesive capsulitis. This study seeks to address this void by investigating the efficacy of MDT on pain, functionality, range of motion (ROM), capsular thickness, quality of life (QoL) in individuals with controlled and uncontrolled stage 2 diabetic adhesive capsulitis.

One of the distinctive contributions of this research lies in its focus on introducing a novel intervention, MDT, which has the potential to offer effective relief for individuals with this challenging condition. By exploring this non-invasive approach, the study aims to enhance pain management, improve functionality, and ultimately elevate the complete quality of life for those affected. Moreover, the inclusion of a follow-up component sets this research apart, offering insights not only into immediate treatment effects but also into the long-term outcomes of MDT. This is crucial for understanding the sustained impact and durability of the intervention over time, providing valuable information for both clinicians and patients.

Furthermore, the study holds significance in bridging existing research gaps and contributing to the broader field of musculoskeletal disorders. The unique intersection of diabetes and adhesive capsulitis poses distinctive challenges, and understanding the potential benefits of MDT in this context can influence future research directions and contribute to evidence-based guidelines. Ultimately, the study's findings may pave the way for expanded treatment options, offering healthcare professionals additional tools to tailor interventions for individuals with diabetic adhesive capsulitis, thereby improving patient outcomes and quality of life.

### Problem Statement

The distinct challenges posed by the combination of adhesive capsulitis and diabetes underscore the need for targeted interventions to address pain, enhance functionality, and mitigate the adverse impact on daily activities. As a non-invasive therapeutic approach, MDT

offers a promising avenue for exploration in this context. Through systematic evaluation and management of diabetic adhesive capsulitis, MDT may provide valuable insights into the potential benefits of this intervention for individuals experiencing stage 2 diabetic adhesive capsulitis.

Furthermore, there exists a scarcity of research that delves into the follow-up outcomes after physical therapy treatments for diabetic adhesive capsulitis. This research gap emphasizes the importance of not only exploring the immediate effects of interventions but also understanding their durability and impact over time. The proposed study, by investigating the efficacy of MDT, not only addresses this void in the literature but also aims to offer a thorough understanding of the potential long-term benefits and sustainability of the intervention for individuals grappling with the challenges of diabetic adhesive capsulitis.

## DESCRIPTION OF TOPIC

Adhesive capsulitis often associated with its heightened prevalence in individuals with diabetes mellitus, stands as a debilitating musculoskeletal disorder distinguished by significant pain and limited range of motion. The repercussions extend to impeding fundamental activities of daily living such as sleeping, dressing, or cooking.

Given the prevalence and impact of adhesive capsulitis, there is a need for more effective and non-invasive treatment options for individuals with stage 2 diabetic adhesive capsulitis. Therefore, the present study is designed to investigate the efficacy of Mechanical Diagnosis and Treatment on pain, functionality, range of motion (ROM), disability, capsular thickness, quality of life (QoL) in individuals with controlled and uncontrolled stage 2 diabetic adhesive capsulitis. This study seeks to provide valuable insights into the potential benefits of Mechanical Diagnosis and Treatment as a non-invasive intervention for managing the symptoms and progression of stage 2 diabetic adhesive capsulitis.

### Operational Definitions

- "Diabetic Adhesive Capsulitis: Adhesive capsulitis of the shoulder, commonly referred to as Frozen Shoulder is a painful and debilitating condition. It is a condition of chronic inflammation and proliferative fibrosis resulting in painful limitation of shoulder movements in diabetic individuals."
- "MDT: A treatment-based approach to shoulder pain assessment and management known as Mechanical Diagnosis and Therapy (MDT) utilizes a classification methodology centred on symptomatic and mechanical responses to end range movements. Patients' conditions are classified into different categories, which guide treatment and establish prognosis: Derangement, Dysfunction and Postural."

## RESEARCH AIM AND OBJECTIVES

### AIM

This study aims to investigate the efficacy of Mechanical Diagnosis and Treatment (MDT) on a comprehensive set of outcomes, including pain, functionality, range of motion (ROM), disability, capsular thickness, quality of life (QoL) in individuals with stage 2 diabetic adhesive capsulitis.

### OBJECTIVES

1. To assess the impact of MDT on pain, function (upper extremity function and ROM), disability, capsular thickness, shoulder strength and overall quality of life in diabetic stage 2 adhesive capsulitis in comparison with conventional treatment.
2. To evaluate the effect of MDT on pain, function (upper extremity function and ROM) and disability in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis.
3. To investigate changes in the capsular thickness after MDT in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis.
4. To examine the influence of MDT on the shoulder strength and overall quality of life in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis.

# METHODOLOGY

## Study Design

A Randomized Controlled Trial (RCT) design with four parallel groups (two intervention and two control groups) will be used, where controlled and uncontrolled diabetic adhesive capsulitis individuals will be randomly assigned separately to one of two different groups (one group will receive intervention and another group is a control). This design allows researchers to compare the effectiveness of one intervention in sub-populations of diabetes mellitus simultaneously, providing valuable insights into their relative efficacy.

## Study Setting

IGESIC Hospital, Jhilmil, New Delhi

## Participants

Participants with controlled and uncontrolled stage 2 diabetic adhesive capsulitis would be included based on exclusion and inclusion criteria.

## Inclusion Criteria

- Both males and females
- Aged between 40-60 years
- Diagnosed case of type 2 diabetes mellitus with atleast 12 months duration having glycosylated haemoglobin (HbA1c) values between 5.5 to 12% treated by diet, oral hypoglycaemic agents or insulin therapy.
- Stage 2 adhesive capsulitis symptoms for atleast three months with >25% restriction in PROM of the shoulder for atleast two directions (shoulder-abduction, -flexion, internal and external rotation) compared to the opposite shoulder.

## Exclusion criteria

- Patients with secondary adhesive capsulitis (e.g. traumatic adhesive capsulitis)
- Subject in inflammatory or chemical stage of adhesive capsulitis (If any 3 of following are present the participant would be excluded: VAS >6, Night pain, redness, increased local temperature morning symptoms).
- Inflammatory arthritis of the shoulder, polyarthritis, rheumatoid arthritis.

- Bony deformity or pre-existing musculoskeletal disorders of the shoulder joint (rotator cuff injury, impingement disorder etc).
- History of shoulder trauma (fractures or dislocations) or ligament injury for <6 months.
- Weakness of shoulder girdle muscles associated with neurological deficits.
- Injection to shoulder pain, invasive procedures or surgeries in the affected shoulder.
- Cervical spondylosis or radiculopathy.
- Uncontrolled comorbidities (moderate to severe anaemia, cardiovascular impairment, nephropathy etc) affecting the study outcomes.
- Subjects with infections and coagulation disorders.
- On medication for adhesive capsulitis.

**Sampling Technique**

This study employs a purposive sampling technique, selecting participants based on accessibility and practical considerations. While this approach expedites data collection, it acknowledges potential limitations in generalizability due to the non-randomized selection of participants. The study prioritizes efficiency within the defined constraints, recognizing the trade-off between practicality and the broader representativeness of the sample.

**Sample size Estimation**

The calculation of the sample size was conducted using G*Power 3.1.9.7 to perform an a priori power analysis. The effect size was calculated using a previous study conducted by Heidar Abady et al. (2017), who studied the effect of MDT on UEFI for derangement, dysfunction and spinal groups at 2 weeks, the effect size came out to be 0.391. The goal was to ascertain the necessary sample size for a study utilizing repeated measures ANOVA between factors analysis. Essential parameters considered in the calculation comprised an effect size of 0.391, an alpha error probability of 0.05, and a desired power of 0.9. The study comprised four groups, each involving four measurements, with a set correlation of 0.5 among these measures. The total sample size came out to be 64. According to the calculations, the total sample size will be 76 (including 20% of dropouts) i.e. 19 participants in each group. This allocation ensures that the study possesses sufficient power to detect the specified effect size with a high level of confidence.

**Randomization and blinding**

In this randomized controlled trial featuring four parallel groups, participants will be randomly assigned into two groups using the block randomization method with a block size of two and allocation ratio of 1:1 using the list of computer-generated random numbers (Separate for controlled and uncontrolled diabetics population).

Group A1 – Control Group will be comprised of subjects with controlled diabetic adhesive capsulitis, HbA1c ≤7%)

Group A2 – Experimental Group will be comprised of subjects with controlled diabetic adhesive capsulitis, HbA1c ≤7%)

Group B1 – Control Group will be comprised of subjects with uncontrolled diabetic adhesive capsulitis, HbA1c >7%)

Group B2 – Experimental Group will be comprised of subjects with uncontrolled diabetic adhesive capsulitis, HbA1c >7%)

Enrolment and assignment of participants will be done by an investigator who will be neither part of the assessment of outcome measures nor implementation of exercise or education. To maintain the study's integrity, a double-blind methodology will be instituted. This approach aims to keep both participants and assessors blinded. The participants will only be explained about the treatment of adhesive capsulitis (the type of intervention/control will not be explained to the participants). The pre-post assessment will be done by the assessor who will not be part of random allocation or treatment.

Blinding is crucial in preventing bias and enhancing the reliability of the study results. The randomization and blinding procedures collectively contribute to a robust study design, facilitating an unbiased evaluation of the intervention's effectiveness under different glycemic control scenarios.

**Variables**

**Dependent Variables**

- Pain
- Functionality:
- Range of Motion
- Disability
- Capsular Thickness
- Quality of Life

**Independent variables**

- Mechanical Diagnosis and Treatment (MDT)

**Procedure**

Detailed demographic information, medical history, and baseline outcome measures will be collected from each participant to establish a comprehensive understanding of their condition. The participants in both the groups will be assessed using the MDT assessment sheet. This will include history taking, observation of posture, palpation, strength and range of motion testing, and special tests. Groups A1 and B1 i.e., control groups 1 and 2 will be advised to follow exercise programs with conventional treatment (i.e. shoulder exercises, pamphlets will be given for the same) along with hot water fomentation as a home program. The participants in groups A2 and B2 i.e., experimental groups 1 and 2, will further be assessed according to MDT approach.

Participants of all the groups would revisit hospital to report changes next day. The treatment would be modified if needed or else he/she will be advised to continue until the symptoms diminish i.e., pain and disability is decreased, and range of motion is increased. Pre-assessment and post-treatment outcome measures will be taken at 2 weeks to evaluate the effectiveness of the interventions. After completing the treatment, participants will be given a home exercise program for prophylaxis. Follow-up assessments will be conducted at 6 and 10 weeks, with outcome measures taken to evaluate the sustainability of treatment effects.

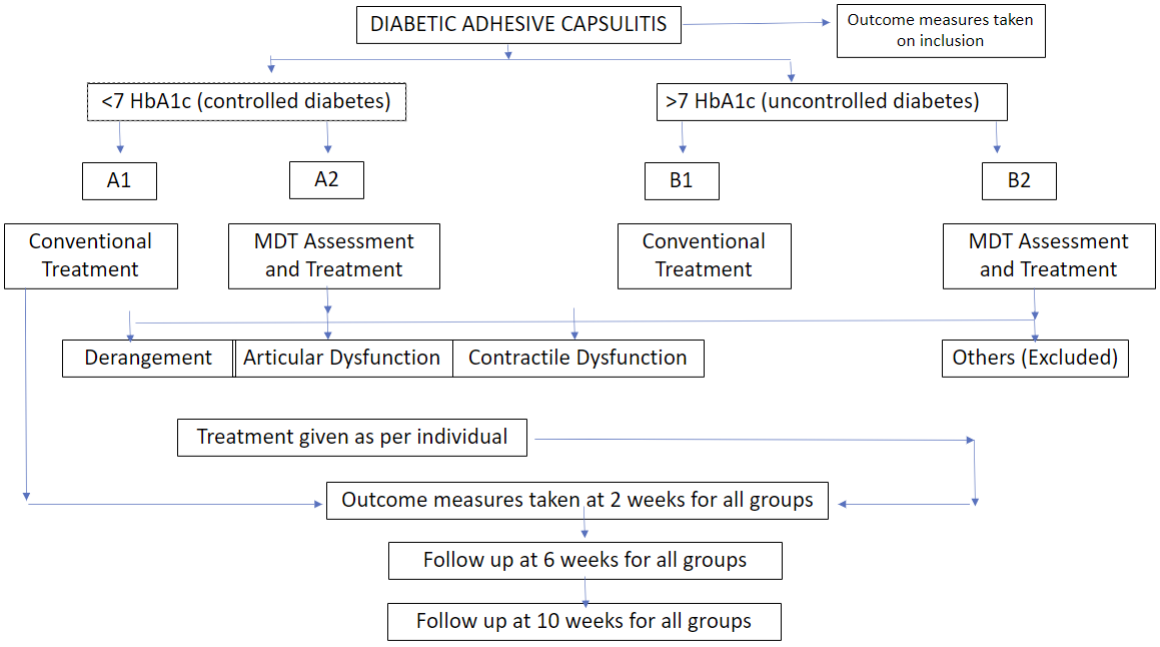



**Figure 1: Outline of the design and progression of the study, providing a visual guide to the research methodology and its various stages.**

**Interventions**

**Mechanical Diagnosis and Treatment (MDT):**

Mechanical Diagnosis and Treatment (MDT) to gather information on the level of pain, duration, nature, and movements affecting the concordant sign using The Mckenzie Institute Upper Extremity Assessment form (Appendix III). MDT approach with a focus on identifying positions or movements that reproduce or alleviate symptoms, known as the concordant sign through which they can be classified into derangement or dysfunction syndrome. The participants will also be advised to take hot water fomentation at home and advised to perform the directional movement identified, for single set of 10-15 repetitions, every one to three hours a day.

**Conventional Treatment**

The participants will be advised to perform self-exercises program included shoulder range of motion exercises, Codman's or pendulum exercises (in different directions) and passive capsular stretching exercises (for inferior and posterior capsule). The participants will be instructed to perform above given exercises in pain-free range while feeling a little stretch. The exercises will be performed two to three times each day. The participants will also be advised to take hot water fomentation at home

**Outcome measures**

1. **Pain**

Pain will be assessed using Visual Analog Scale (VAS). VAS is a standardized tool for participants to self-report pain intensity on a scale.

2. **Functionality**

Upper extremity function will be assessed using Upper Extremity Functional Index (UEFI). UEFI is a validated self-reported measure for quantifying upper extremity function in individuals with musculoskeletal problems.

3. **Range of Motion**

Range of motion will be assessed by universal goniometer. Universal goniometer is a reliable tool to assess and quantify the range of motion in various shoulder movements.

**4. Disability**

The Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire is a self-administered instrument crafted to assess self-rated upper-extremity disability and associated symptoms. This tool is specifically designed to provide individuals with a means to articulate their subjective experiences related to arm, shoulder, and hand disabilities.

**5. Capsular Thickness**

Capsular thickness and coracohumeral ligament (CHL) thickness will be assessed by Magnetic Resonance Imaging (MRI) Reports of the shoulder joint. Thickening of capsule and CHL on MRI showed moderate to high sensitivity and specificity (Mengiardi et al., 2004).

**6. Quality of Life**

Standardized Quality of Life (QoL) Assessment Tools will be implemented as a validated tools to assess the overall quality of life of participants.

## EXPECTED OUTCOME OF THE RESEARCH

**Null Hypotheses ($H_0$):**

- There is no statistically significant difference of the impact of MDT on pain, function (upper extremity function and ROM), disability, capsular thickness, shoulder strength and overall quality of life in diabetic stage 2 adhesive capsulitis in comparison with conventional treatment.
- The effect of MDT on pain, function (upper extremity function and ROM) and disability in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis is significantly not different.
- There is no significant difference in changes in the capsular thickness after MDT in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis.
- The influence of MDT on the shoulder strength and overall quality of life in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis is not statistically significant.

**Alternative Hypotheses ($H_1$):**

- There is a significant difference of the impact of MDT on pain, function (upper extremity function and ROM), disability, capsular thickness, shoulder strength and overall quality of life in diabetic stage 2 adhesive capsulitis in comparison with conventional treatment.
- The effect of MDT on pain, function (upper extremity function and ROM) and disability in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis is significantly different.
- There is a significant difference in changes in the capsular thickness after MDT in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis.
- The influence of MDT on the shoulder strength and overall quality of life in individuals with controlled and uncontrolled diabetic stage 2 adhesive capsulitis is statistically significant.

## REFERENCES


Adams, A. L., Paxton, E. W., Wang, J. Q., Johnson, E. S., Bayliss, E. A., Ferrara, A., ... & Namba, R. S. (2013). Surgical outcomes of total knee replacement according to diabetes status and glycemic control, 2001 to 2009. JBJS, 95(6), 481-487.

Aina, A., & May, S. (2005). A shoulder derangement. Manual Therapy, 10(2), 159-163.

Arkkila, P. E., & Gautier, J. F. (2003). Musculoskeletal disorders in diabetes mellitus: an update. Best practice & research Clinical rheumatology, 17(6), 945-970.

Bowman, C. A., Jeffcoate, W. J., Pattrick, M., & Doherty, M. (1988). Case report: bilateral adhesive capsulitis, oligoarthritis and proximal myopathy as presentation of hypothyroidism. Rheumatology, 27(1), 62-64.

Bowser, A., & Swanson, B. T. (2016). Evaluation and treatment of a patient diagnosed with adhesive capsulitis classified as a derangement using the McKenzie method: a case report. International Journal of Sports Physical Therapy, 11(4), 627.

Cagliero, E., Apruzzese, W., Perlmutter, G. S., & Nathan, D. M. (2002). Musculoskeletal disorders of the hand and shoulder in patients with diabetes mellitus. The American journal of medicine, 112(6), 487-490.

Chen, C. Y., Hu, C. C., Weng, P. W., Huang, Y. M., Chiang, C. J., Chen, C. H., ... & Cheng, C. K. (2014). Extracorporeal shockwave therapy improves short-term functional outcomes of shoulder adhesive capsulitis. Journal of shoulder and elbow surgery, 23(12), 1843-1851.

Choi, Y. H., & Kim, D. H. (2020). Correlations between clinical features and MRI findings in early adhesive capsulitis of the shoulder: a retrospective observational study. BMC Musculoskeletal Disorders, 21, 1-9.

Codman, E. A. (1934). Rupture of the supraspinatus tendon and other lesions in and about the subacromial bursa. The shoulder.

Ewald, A. (2011). Adhesive Capsulitis: A Review. American Family Physician, 83(4), 417-422.

Fields, B. K., Skalski, M. R., Patel, D. B., White, E. A., Tomasian, A., Gross, J. S., & Matcuk, G. R. (2019). Adhesive capsulitis: review of imaging findings, pathophysiology, clinical presentation, and treatment options. Skeletal radiology, 48, 1171-1184.

Hannafin, J. A., & Chiaia, T. A. (2000). Adhesive capsulitis: a treatment approach. Clinical Orthopaedics and Related Research®, 372, 95-109.

Heidar Abady, A., Rosedale, R., Chesworth, B. M., Rotondi, M. A., & Overend, T. J. (2017). Application of the McKenzie system of Mechanical Diagnosis and Therapy (MDT) in patients with shoulder pain; a prospective longitudinal study. Journal of Manual & Manipulative Therapy, 25(5), 235-243.

Kelley, M. J., Shaffer, M. A., Kuhn, J. E., Michener, L. A., Seitz, A. L., Uhl, T. L., ... & Wilk, K. (2013). Shoulder pain and mobility deficits: adhesive capsulitis: clinical practice guidelines linked to the international classification of functioning, disability, and health from the Orthopaedic Section of the American Physical Therapy Association. Journal of orthopaedic & sports physical therapy, 43(5), A1-A31.

Massoud, S. N., Pearse, E. O., Levy, O., & Copeland, S. A. (2002). Operative management of the frozen shoulder in patients with diabetes. Journal of shoulder and elbow surgery, 11(6), 609-613.

McKenzie, R. (2006). The cervical and thoracic spine: mechanical diagnosis and therapy.

McKenzie, R. A., & May, S. (1981). The lumbar spine. Mechanical diagnosis & therapy, 1, 374.

Mengiardi, B., Pfirrmann, C. W., Gerber, C., Hodler, J., & Zanetti, M. (2004). Frozen shoulder: MR arthrographic findings. Radiology, 233(2), 486-492.

Metgud, S., Naik, S., & Heggannavar, A. (2017). Effect of McKenzie method of Mechanical Diagnosis and Therapy (MDT) on pain, range of motion and shoulder functions using Penn shoulder score in individuals with stage ii adhesive capsulitis: A pre-post experimental study.

Mueller, M. J., Sorensen, C. J., McGill, J. B., Clark, B. R., Lang, C. E., Chen, L., ... & Hastings, M. K. (2018). Effect of a shoulder movement intervention on joint mobility, pain, and disability in people with diabetes: a randomized controlled trial. Physical therapy, 98(9), 745-753.

Nakandala, P., Nanayakkara, I., Wadugodapitiya, S., & Gawarammana, I. (2021). The efficacy of physiotherapy interventions in the treatment of adhesive capsulitis: A systematic review. Journal of back and musculoskeletal rehabilitation, 34(2), 195-205.

Neviaser, A. S., & Hannafin, J. A. (2010). Adhesive capsulitis: a review of current treatment. The American journal of sports medicine, 38(11), 2346-2356.

Neviaser, A. S., & Neviaser, R. J. (2011). Adhesive capsulitis of the shoulder. JAAOS-Journal of the American Academy of Orthopaedic Surgeons, 19(9), 536-542.

Neviaser, J. S. (1945). Adhesive capsulitis of the shoulder: a study of the pathological findings in periarthritis of the shoulder. JBJS, 27(2), 211-222.

Ogilvie-Harris, D. J., & Myerthall, S. (1997). The diabetic frozen shoulder: arthroscopic release. Arthroscopy: The Journal of Arthroscopic & Related Surgery, 13(1), 1-8.

Page, P., & Labbe, A. (2010). Adhesive capsulitis: use the evidence to integrate your interventions. North American journal of sports physical therapy: NAJSPT, 5(4), 266.

Ramirez, J. (2019). Adhesive capsulitis: diagnosis and management. American family physician, 99(5), 297-300.

Redler, L. H., & Dennis, E. R. (2019). Treatment of adhesive capsulitis of the shoulder. JAAOS-Journal of the American Academy of Orthopaedic Surgeons, 27(12), e544-e554.

Remsburg, J. (2019). Chiropractic and Mckenzie method assessment and treatment of a patient with a shoulder derangement mimicking adhesive capsulitis. Journal of Contemporary Chiropractic, 2(1), 54-59.

Rodeo, S. A., Hannafin, J. A., Tom, J., Warren, R. F., & Wickiewicz, T. L. (1997). Immunolocalization of cytokines and their receptors in adhesive capsulitis of the shoulder. Journal of Orthopaedic Research, 15(3), 427-436.

Sofka, C. M., Ciavarra, G. A., Hannafin, J. A., Cordasco, F. A., & Potter, H. G. (2008). Magnetic resonance imaging of adhesive capsulitis: correlation with clinical staging. HSS Journal®, 4(2), 164-169.

Tanaka, K., Saura, R., Takahashi, N., Hiura, Y., & Hashimoto, R. (2010). Joint mobilization versus self-exercises for limited glenohumeral joint mobility: randomized controlled study of management of rehabilitation. Clinical rheumatology, 29, 1439-1444.

Tighe, C. B., & Oakley Jr, W. S. (2008). The prevalence of a diabetic condition and adhesive capsulitis of the shoulder. Southern medical journal, 101(6), 591-595.

Watson, R. S., Gouze, E., Levings, P. P., Bush, M. L., Kay, J. D., Jorgensen, M. S., ... & Ghivizzani, S. C. (2010). Gene delivery of TGF-β1 induces arthrofibrosis and chondrometaplasia of synovium in vivo. Laboratory investigation, 90(11), 1615-1627.

Wohlgethan, J. R. (1987). Frozen shoulder in hyperthyroidism. Arthritis & Rheumatism: Official Journal of the American College of Rheumatology, 30(8), 936-939.

Wong, P. L. K., & Tan, H. C. A. (2010). A Review on Frozen Shoulder. Singapore Medical Journal, 51(9), 694.

Zreik, N. H., Malik, R. A., & Charalambous, C. P. (2016). Adhesive capsulitis of the shoulder and diabetes: a meta-analysis of prevalence. Muscles, ligaments and tendons journal, 6(1), 26.

Zuckerman, J. D., & Rokito, A. (2011). Frozen shoulder: a consensus definition. Journal of shoulder and elbow surgery, 20(2), 322-325.

## APPENDIX I

SCREENING FORM

Name:

Age:

Gender:

Height:

Weight:

BMI:

Address:

Contact:

| | **YES** | **NO** |
|---|---|---|
| Is there presence of Diabetes? | | |
| HbA 1 c level (if applicable) | | |
| Do you have any night pain? | | |
| Do you have any History of fractures, dislocations less than 6 months? | | |
| Did you have Shoulder ligament injuries < 6mths / traumatic adhesive capsulitis? | | |
| Do you have any cardiac conditions, infections or coagulation disorders. | | |

## APPENDIX II

DATA COLLECTION FORM

NAME:

AGE:

GENDER:

GROUP:

| OUTCOME MEASURES | PRE | POST | FOLLOW UP 1 | FOLLOW UP 2 |
|---|---|---|---|---|
| VAS SCORE | | | | |
| RANGE OF MOTION | | | | |
| UEFI SCORE | | | | |
| DASH SCORE | | | | |
| CAPSULAR THICKNESS | | | | |

## APPENDIX III

### THE McKENZIE INSTITUTE
### UPPER EXTREMITIES ASSESSMENT

Date _____

Name _____ Sex M / F

Address _____

Telephone _____

Date of Birth _____ Age _____

Referral: *GP / Oth / Self / Other* _____

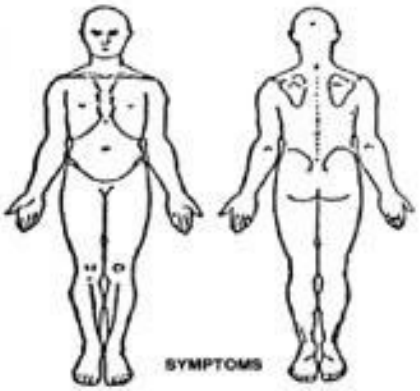
Work: Mechanical stresses _____

Leisure: Mechanical stresses _____

Functional Disability from present episode _____

Functional Disability score _____

VAS Score (0-10) _____




**HISTORY** **Handedness: Right / Left**

Present Symptoms _____

Present since _____ *Improving / Unchanging / Worsening*

Commenced as a result of _____ *Or No Apparent Reason*

Symptoms at onset _____ Paraesthesia: Yes / No

Spinal history _____ Cough /Sneeze +ve / -ve

Constant symptoms: _____ Intermittent Symptoms: _____

**Worse** *bending sitting turning neck dressing reaching gripping*
*am / as the day progresses / pm when still / on the move* Sleeping: *prone / sup / side R / L*
*Other* _____

**Better** *bending sitting turning neck dressing reaching gripping*
*am / as the day progresses / pm when still / on the move* Sleeping: *prone / sup / side R / L*
*other* _____

Continued use makes the pain: *Better Worse No Effect* Disturbed night: *Yes / No*

Pain at rest: *Yes / No* Site: *Neck / Shoulder / Elbow / Wrist / Hand*

Other Questions: *Swelling Catching / Clicking / Locking Subluxing*

Previous episodes _____

Previous treatments _____

General health: *Good / Fair / Poor* _____

Medications: *Nil / NSAIDS / Analg / Steroids / Anticoag / Other* _____

Imaging: *Yes / No* _____

Recent or major surgery: *Yes / No* _____ Night pain: *Yes / No* _____

Accidents: *Yes / No* _____ Unexplained weight loss: *Yes / No*

**Summary** *Acute / Sub-acute / Chronic* *Trauma / Insidious Onset*

Sites for physical examination: *Neck / Shoulder / Elbow / Wrist / Hand* *Other:* _____

*© Copyright The McKenzie Institute International 2014* June 2014

## EXAMINATION

**POSTURE**

Sitting *Good / Fair / Poor* Correction of Posture: *Better / Worse / No Effect / NA* Standing: *Good / Fair / Poor*

Other observations: _____

**NEUROLOGICAL:** **NA / Motor / Sensory / Reflexes / Dural** _____

**BASELINES (pain or functional activity):** _____

**EXTREMITIES** ***Shoulder / Elbow / Wrist / Hand*** _____

| MOVEMENT LOSS | Maj | Mod | Min | Nil | Pain |
|---|---|---|---|---|---|
| Flexion | | | | | |
| Extension | | | | | |
| Supination | | | | | |
| Pronation | | | | | |
| | | | | | |

| | Maj | Mod | Min | Nil | Pain |
|---|---|---|---|---|---|
| Adduction / Ulnar Deviation | | | | | |
| Abduction / Radial Deviation | | | | | |
| Internal Rotation | | | | | |
| External Rotation | | | | | |
| | | | | | |

**Passive Movement (+/- over pressure) (note symptoms and range):** _____

| PDM | ERP |
|---|---|
| | |
| | |
| | |

**Resisted Test Response (pain)** _____

**Other Tests** _____

**SPINE**

Movement Loss _____

Effect of repeated movements _____

Effect of static positioning _____

Spine testing *Not relevant / Relevant / Secondary problem* _____

**Baseline Symptoms** _____

| Repeated Tests | Symptom Response | | Mechanical Response | |
|---|---|---|---|---|
| **Active / Passive movement, resisted test, functional test** | **During –** Produce, Abolish, Increase, Decrease, NE | **After –** Better, Worse, NB, NW, NE | **Effect –** ↑ or ↓ ROM, strength or key functional test | No Effect |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| **Effect of static positioning** | | | | |
| | | | | |

**PROVISIONAL CLASSIFICATION** **Extremities** **Spine**

Dysfunction – Articular _____ Contractile _____

Derangement _____ Postural _____

Other _____ Uncertain _____

**PRINCIPLE OF MANAGEMENT**

Education _____ Equipment Provided _____

Exercise and Dosage _____

Treatment Goals _____

© Copyright The McKenzie Institute International 2014

June 2014

# Patient Information Sheet & Consent form

*(Note: Provide adequate information in a simple, non-technical, and comprehensible language to the participants so that they can decide to participate / not to participate. The following points should preferably be covered) –*

## Part I: Patient information sheet

1. Title of the study

   Efficacy of Mechanical Diagnosis and Treatment on Pain, Functionality and Capsular Thickness in Individuals with Stage 2 Diabetic Adhesive Capsulitis

2. Name of the PI / Co-PI

   Sheena Arora / Dr. Kshitija Bansal / Dr. Khyatee

3. Funding / Sponsor

   NA

4. Invitation paragraph

   I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or the study staff.

5. Purpose of the study

   The current study is going to find out the effect of Mechanical Diagnosis and Treatment (MDT) for examination and intervention in subjects with diabetic adhesive capsulitis. As MDT focuses on self-management and education of the disorder so this study intends to find out the measures that can be used to educate patients to self manage the disorder leading to lesser number of follow up visits and greater satisfaction with quality of life in patients.

6. Why the subject has been selected

   As diabetes is one of the most common disorders and this condition is more likely to develop in diabetics by almost 13%, that is five times greater than non-diabetics. Diabetes mellitus has also been observed in 30% of individuals with adhesive capsulitis. It is known that diabetes delays the healing process and the condition can relapse so follow up has also been taken in the study. More over the type of diabetes i.e. controlled and uncontrolled can have further impact on healing and this study intends to find out the same.

7. Study design

   RCT with 4 parallel groups (2 intervention and 2 control group)

8. Procedure being studied

   You are being included in our study on the basis of pre-decided exclusion and inclusion criteria. Demographic details and outcome measures would be taken.
   Assessment – You would be assessed using Mechanical Diagnosis and Treatment (MDT) McKenzie Method. This approach involves identifying the level of pain in the body area involved, duration and nature of the pain, and positions or movement that alter the same.
   After conducting history taking and examination, you will be randomly allocated into one of the two groups receiving intervention but you and your assessor will be blinded to the treatment you are receiving.
   You will have to revisit the institution to report changes every alternate day till 2 weeks. The treatment would be modified if needed or else you will be advised to continue till the symptoms lessen i.e., pain and disability is decreased, and range of motion is increased.
   Outcome measures will be taken pre assessment and post treatment at 2 weeks.
   After completing the treatment, the subjects would be given home exercise program as prophylaxis, and you will be called for follow-up after 6 as well as 10 weeks and again outcome measures will be taken.

9. Who has reviewed the study?

   This research has been reviewed and approved by Institutional Ethics Committee (IEC) of PDUNIPPD / and Ethical committee at Manav Rachna International Institute of Research and Studies which is a committee whose task it is to make sure that research participants are protected from harm.

10. Possible risks to the participants

    By participating in this research, you will be at no risk.

11. Possible benefits to the participants

    You will be provided the treatment and assessments free of cost.

12. Compensation

    You will not be able to receive any compensation for the inconvenience and travel. You will benefit from being on this research study in terms of free treatment and assessments even after the completion of / withdrawal from the study.

13. Possible benefits to other people

    There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit. The results of the research may provide benefits to the

society in terms of advancement of medical knowledge and/or therapeutic benefit to future patients.

14. Alternatives available to the participants

    If you do not wish to take part in the research, you will be provided with the established standard treatment available at the Institute.

15. Right to Refuse or Withdraw

    You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this Institute in any way. You will still have all the benefits that you would otherwise have at this Institute. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here.

16. Cost to the participant

    No cost for participation.

17. What should the participant do in case of injury or a medical problem during this research study?

    You will be referred to relevant nearby hospital.

18. Confidentiality of the information obtained from the participants

    The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. By signing this document, you will be allowing the research team investigators, other study personnel, PDUNIPPD ethics committee and any person or agency required by law to view your data, if required. The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

19. How will the decision to not participate in the study affect the subject?

    You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. You will still have all the benefits that you would otherwise have at this Institute.

20. Can one decide to stop participating in the study after the start?

    You can withdraw yourself at any point from the study. It will not affect your treatment at this Institute in any way.

21. Can the investigator take participant off the study?

    You may be taken off the study without your consent if you do not follow instructions of the investigators or if the investigator thinks that further participation may cause you harm.

22. Right to new information

    The knowledge that we get from doing this research will be shared with the similar professionals through presentation and publication for the benefit of the society. You will also have rights to know the outcome of the study. However, confidential information will not be shared.

23. Contact for further information

    If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
    Sheena Arora – sheena.arora.81989@gmail.com, 8820744801
    Research Scholar
    Dr. (Prof.) Kshitija Bansal – kshitijabansal.sahs@mriu.edu.in, 9810314488
    Supervisor
    Dr. Khyatee – drkhyatee1980@gmail.com , 9999387423
    Joint Supervisor
    Dr Kamal Narayan Arya - pdunippdiec@gmail.com, 9899897408
    Lecturer OT, Member Secretary IEC

## Part II: Consent Form

Study title: Efficacy of Mechanical Diagnosis and Treatment on Pain, Functionality and Capsular Thickness in Individuals with Stage 2 Diabetic Adhesive Capsulitis

Name of PI: Sheena Arora

Subjects Name & Detail:

**Consent**

1. I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.
OR
I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the investigators, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)
5. I agree to take part in the above study

Signature / Thumb impression of subject: _____
Name of Subject: _____
Date: _____

Investigator's statement:

I, the undersigned have explained to the patient in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signatures of the Investigators:
Name of the Investigator:
Date:

Signature of the Witness:
Name of the Witness:
Date:

रोगी सूचना शीट एवं सहमति फॉर्म

(नोट: प्रतिभागियों को सरल, गैर-तकनीकी और साधारण भाषा में सूचना उपलब्ध करवाएँ जिससे कि वे सहभागिता करने या न करने पर निर्णय लें सकें। निम्न बिंदु अवश्य सम्मिलित होने चाहिए)

भाग-1: रोगी सूचना शीट

1. **अध्ययन का शीर्षक**

   स्टेज 2 डायबिटिक एडहेसिव कैप्सुलिटिस वाले व्यक्तियों में दर्द, कार्यक्षमता और कैप्सुलर मोटाई पर मैकेनिकल डायग्नोसिस एंड ट्रीटमेंट की प्रभावकारिता

2. **पीआई का नाम / सह-पीआई**

   शीना अरोड़ा/डॉ. क्षितिजा बंसल/डॉ. ख्याति

3. **अनुदान / प्रयोजक**

   लागू नहीं

4. **आमंत्रण पैराग्राफ**

   मैं आपको सूचना प्रदान करने जा रही हूँ और इस अध्ययन में शामिल होने के लिए आमंत्रित कर रही हूँ। आपको आज ही निर्णय नहीं लेना है कि आप अध्ययन में सहभागिता करेंगे या नहीं। आप अध्ययन के बारे में निर्णय लेने से पहले किसी से सहजता पूर्वक बात कर सकते हैं। ऐसे कुछ शब्द हो सकते हैं जिनसे आप अपरिचित हों। आप मुझे रुकने के लिए कहें और मैं आपको विस्तार से समय लेकर समझाउंगी। यदि बाद में आप अध्ययन संबंधी प्रश्न पूछना चाहते हैं तो आप मुझसे प्रश्न पूछ सकते हैं।

5. **अध्ययन का उद्देश्य**

   (साधारण शब्दों में व्याख्या करें कि आप अध्ययन क्यों कर रहे हैं)

   वर्तमान अध्ययन डायबिटिक एडहेसिव कैप्सुलिटिस वाले विषयों में जांच और हस्तक्षेप के लिए मैकेनिकल डायग्नोसिस एंड ट्रीटमेंट (एमडीटी) के प्रभाव का पता लगाने जा रहा है। चूंकि एमडीटी विकार के स्व-प्रबंधन और शिक्षा पर ध्यान केंद्रित करता है, इसलिए इस अध्ययन का उद्देश्य उन उपायों का पता लगाना है जिनका उपयोग रोगियों को विकार को स्वयं प्रबंधित करने के लिए शिक्षित करने के लिए किया जा

सकता है, जिससे अनुवर्ती यात्राओं की संख्या कम हो और रोगियों में जीवन की गुणवत्ता के साथ अधिक संतुष्टि हो।

**6. इस विषय का चयन क्यों किया गया**

चूंकि मधुमेह सबसे आम विकारों में से एक है और मधुमेह रोगियों में इस स्थिति के विकसित होने की संभावना लगभग 13% अधिक है, जो गैर-मधुमेह रोगियों की तुलना में पांच गुना अधिक है। चिपकने वाले कैप्सुलिटिस वाले 30% व्यक्तियों में मधुमेह भी देखा गया है। यह ज्ञात है कि मधुमेह उपचार प्रक्रिया में देरी करता है और स्थिति फिर से उत्पन्न हो सकती है, इसलिए अध्ययन में अनुवर्ती भी कार्रवाई गई है। मधुमेह के प्रकार यानी नियंत्रित और अनियंत्रित होने से उपचार पर और अधिक प्रभाव पड़ सकता है और इस अध्ययन का उद्देश्य यही पता लगाना है।

**7. अध्ययन डिजाइन**

4 समानांतर समूहों के साथ आरसीटी (2 हस्तक्षेप और 2 नियंत्रण समूह)

**8. जिस पद्धति का अध्ययन किया जा रहा है**

**(**चरण दर चरण होने वाली सटीक प्रक्रिया का वर्णन अथवा व्याख्या करें)

आपको पूर्व-निर्धारित बहिष्करण और समावेशन मानदंडों के आधार पर हमारे अध्ययन में शामिल किया जा रहा है। जनसांख्यिकीय विवरण और परिणाम उपाय किए जाएंगे।

मूल्यांकन - आपका मूल्यांकन मैकेनिकल डायग्नोसिस एंड ट्रीटमेंट (एमडीटी) मैकेंजी पद्धति का उपयोग करके किया जाएगा। इस दृष्टिकोण में शामिल शरीर क्षेत्र में दर्द के स्तर, दर्द की अवधि और प्रकृति, और स्थिति या आंदोलन की पहचान करना शामिल है जो इसे बदलता है।

इतिहास लेने और जांच करने के बाद, आपको हस्तक्षेप प्राप्त करने वाले दो समूहों में से एक में यादृच्छिक रूप से आवंटित किया जाएगा, लेकिन आप और आपके मूल्यांकनकर्ता को आपके द्वारा प्राप्त किए जा रहे उपचार के बारे में पता नहीं चलेगा।

आपको 2 सप्ताह तक हर दूसरे दिन परिवर्तन की रिपोर्ट करने के लिए संस्थान में दोबारा आना होगा। यदि आवश्यक हो तो उपचार को संशोधित किया जाएगा अन्यथा

आपको लक्षण कम होने तक उपचार जारी रखने की सलाह दी जाएगी, यानी दर्द और विकलांगता कम हो जाती है, और गति की सीमा बढ़ जाती है।

2 सप्ताह में मूल्यांकन से पहले और उपचार के बाद परिणामी उपाय किए जाएंगे। उपचार पूरा करने के बाद, लोगों को प्रोफिलैक्सिस के रूप में घरेलू व्यायाम कार्यक्रम दिया जाएगा, और आपको 6 और 10 सप्ताह के बाद फॉलो-अप के लिए बुलाया जाएगा और फिर से परिणामी उपाय किए जाएंगे।

**9. अध्ययन की समीक्षा किसने की है?**

इस अध्ययन की समीक्षा एवं स्वीकृति संस्थान की संस्थागत आचार समिति (आईईसी) द्वारा दी गई है और इस समिति का उद्देश्य है कि शोध में भाग लेने वाले सहभागियों की सुरक्षा सुनिश्चित की जा सके।

**10.सहभागियों को होने वाले संभाव्य जोखिम**

इस शोध में सम्मिलित होने पर आप को कोई जोखिम नहीं / न्यूनतम से कम / न्यूनतम / कम जोखिम होगा।

**11.सहभागियों को होने वाले संभाव्य लाभ**

आपको इलाज और आकलन नि:शुल्क उपलब्ध करवाया जाएगा।

**12.प्रतिपूर्ति**

आपको हुई असुविधा एवं यात्रा के लिए आप प्रतिपूर्ति के हकदार नहीं होंगे। आप इस अध्ययन से नि:शुल्क इलाज और आकलन की सुविधा आपने के हकदार होंगे और यह सुविधा अध्ययन पूरा होने / नाम वापिस लेने पर भी जारी रहेगी।

**13.अन्य व्यक्तियों को संभाव्य लाभ**

शोध के इस चरण पर समाज को कोई लाभ नहीं होगा परंतु आने वाली पीढ़ियों को लाभ होगा। इस शोध के परिणाम से समाज में भावी मरीजों को चिकित्सा ज्ञान में वृद्धि और / या चिकित्सीय लाभ होगा।

**14.सहभागियों को उपलब्ध विकल्प**

यदि आप इस शोध में सम्मिलित नहीं होना चाहते तो आपको संस्थान में उपलब्ध मानक चिकित्सा इलाज प्रदान करवाया जाएगा।

**15.मना करने या नाम वापिस लेने के अधिकार**

यदि आप इस शोध में सम्मिलित नहीं होंगे या मना कर देते हैं तो वह किसी भी स्थिति में इस संस्थान में होने वाले आपके इलाज पर कोई प्रभाव नहीं डालेगा। आपको संस्थान से अभी भी सभी लाभ प्राप्त होंगे जो आपको अन्यथा भी मिलते। आप एक रोगी होने के अधिकार से शोध से किसी भी समय अपनी सहभागिता वापिस ले सकते हैं।

**16.प्रतिभागी के लिए लागत**

भागीदारी के लिए कोई शुल्क नहीं

**17.शोध अध्ययन के दौरान प्रतिभागी के घायल होने अथवा चिकित्सा समस्या होने पर क्या करना चाहिए?**

आपको संबंधित नजदीकी अस्पताल में रेफर किया जाएगा।

**18.प्रतिभागियों से प्राप्त सूचना की गोपनीयता**

इस शोध परियोजना के लिए एकत्रित की गई सूचना गोपनीय रखी जाएगी। शोध के दौरान एकत्रित की गई सूचना को शोधकर्ताओं के अलावा कोई भी नहीं देख पाएगा। आपकी सूचना को आपके नाम के बजाए एक संख्या आवंटित की जाएगी। केवल शोधकर्ताओं को ही आपकी संख्या का पता होगा और हम उस सूचना को लॉक कर देंगे जोकि की **(key)** द्वारा देख पाएंगे। यह किसी के साथ साझा नहीं की जाएगी। इस दस्तावेज़ पर हस्ताक्षर करने के पश्चात, आप कानूनी रूप से शोध टीम अन्वेषक, अन्य अध्ययनकर्ता, संस्थान की आचार समिति और अन्य किसी व्यक्ति / अभिकरण के साथ आवश्यकता पड़ने पर अपने डेटा को साझा करने की अनुमति प्रदान करेंगे। इस शोध में शामिल होने के लिए आप पर किए गए नैदानिक परीक्षण और चिकित्सा परिणामों को आपके चिकित्सीय रेकॉर्ड में शामिल किया जा सकता है। यदि इस शोध की सूचना किसी वैज्ञानिक पत्रिकाओं और वैज्ञानिक बैठकों में प्रस्तुत की जाती है उसमें आपकी पहचान गुप्त रखी जाएगी।

**19.इस शोध में सहभागिता न करने का निर्णय विषय को कैसे प्रभावित करेगा**?

आप एक रोगी के अधिकारों को बिना खोए किसी भी समय इस शोध में सम्मिलित न होने से मना कर सकते हैं। आपके पास सभी लाभ होंगे जो आपको संस्थान में अन्यथा भी मिलते।

**20.क्या अध्य्यन प्रारंभ होने के पश्चात कोई शोध में सम्मिलित होने से मना कर सकता है**?

यदि आप इस शोध में सम्मिलित नहीं होंगे या मना कर देते हैं तो वह किसी भी स्थिति में इस संस्थान में होने वाले आपके इलाज पर कोई प्रभाव नहीं डालेगा।

**21.क्या अन्वेषक प्रतिभागी को अध्ययन से हटा सकता है**?

यदि आप अन्वेषकों द्वारा दिए गए दिशा-निर्देशों का पालन नहीं करते हैं तो आपकी सहमति के बिना आपको शोध से हटाया जा सकता है अथवा यदि अन्वेषक को लगता है कि आपकी सहभागिता आपको नुकसान पहुँचा सकती है।

**22.नई सूचना का अधिकार**

इस शोध के दौरान एकत्रित किया गया ज्ञान समाज कल्याण के लिए केवल इसी क्षेत्र के पेशेवरों के साथ प्रस्तुतीकरण एवं प्रकाशन के द्वारा ही साझा किया जाएगा। आपको अध्य्यन का परिणाम जानने का भी अधिकार होगा। यद्यपि, गोपनीय सूचना साझा नहीं की जाएगी।

**23.आगे की जानकारी के लिए संपर्क**

आप कोई प्रश्न अभी या बाद में या अध्ययन प्रारंभ होने के पश्चात पूछ सकते हैं। यदि आप प्रश्न बाद में पूछना चाहते हैं तो इनमें से किसी से भी संपर्क कर सकते हैं:

शीना अरोड़ा - sheena.arora.81989@gmail.com, 8820744801
Research Scholar
डॉ. (प्रो.) क्षितिजा बंसल - kshitijabansal.sahs@mriu.edu.in, 9810314488
Supervisor
डॉ ख्याति - drkhyatee1980@gmail.com , 9999387423
Joint Supervisor
डॉ. कमल नारायण आर्य - pdunippdiec@gmail.com, 9899897408
Lecturer OT, Member Secretary IEC

भाग **II:** सहमति फॉर्म

अध्ययन शीर्षक और कोड संख्या:

पीआई का नाम:

विषयों का नाम एवं विवरण:

सहमति

1. मैं पुष्टि करता / करती हूँ कि मैंने उपर्युक्त अध्ययन के लिए दिनांक.....की सूचना शीट को पढ़ और समझ लिया है और प्रश्न पूछने का अवसर मिला है।

   अथवा

   अन्वेषक द्वारा मुझे अध्ययन के प्रकार के बारे में समझा दिया गया है और मुझे प्रश्न पूछने का अवसर मिला था।
2. मैं समझता / समझती हूँ कि इस अध्ययन में मेरी सहभागिता स्वैच्छिक है और मैं किसी भी समय बिना कोई कारण बताए और बिना किसी चिकित्सीय देखभाल और कानूनी अधिकारों के हनन के बिना अपना नाम वापिस ले सकता / सकती हूँ।
3. मैं समझता / समझती हूँ कि अन्वेषक, आचार समिति और विनियामक प्राधिकारियों को चालू अध्ययन और किसी भावी अध्ययन के लिए और ट्रायल से मेरे नाम वापिस लेने की स्थिति में भी, मेरे स्वास्थ्य रेकॉर्ड देखने के लिए मेरी अनुमति लेने की आवश्यकता नहीं है। यद्यपि, मैं समझता / समझती हूँ कि तृतीय पक्ष को प्रदान करने वाली सूचना में या प्रकाशित होने वाली सूचना में मेरी पहचान गुप्त रखी जाएगी।
4. मैं इस अध्ययन से प्राप्त डेटा या परिणाम को प्रयोग करने की अनुमति प्रदान करता / करती हूँ बशर्ते वो केवल वैज्ञानिक परिणाम (मों) के लिए प्रयुक्त हो।
5. मैं उक्त अध्ययन में भाग लेने के लिए सहमति प्रदान करता हूँ / करती हूँ।

हस्ताक्षर / अंगूठे का निशान

विषय:.....

विषय का नाम:.....

दिनांक.....

अन्वेषकों का ब्यान

मैं, अधोहस्ताक्षरी ने अध्ययन में होने वाले जोखिम और लाभों को रोगी की भाषा में समझा दिया है।

अन्वेषकों के हस्ताक्षर:

अन्वेषक का नाम:

दिनांक:

गवाहों के हस्ताक्षर:

दिनांक:

# The Upper Extremity Functional Index (UEFI)

We are interested in knowing whether you are having any difficulty at all with the activities listed below **because of your upper limb** problem for which you are currently seeking attention. Please provide an answer for **each** activity.

**Today, *do you* or *would you* have any difficulty at all with:**

| | Activities | Extreme difficulty or unable to perform activity | Quite a bit of difficulty | Moderate difficulty | A little bit of difficulty | No difficulty |
|---|---|---|---|---|---|---|
| 1 | Any of your usual work, housework, or school activities | 0 | 1 | 2 | 3 | 4 |
| 2 | Your usual hobbies, recreational or sporting activities | 0 | 1 | 2 | 3 | 4 |
| 3 | Lifting a bag of groceries to waist level | 0 | 1 | 2 | 3 | 4 |
| 4 | Lifting a bag of groceries above your head | 0 | 1 | 2 | 3 | 4 |
| 5 | Grooming your hair | 0 | 1 | 2 | 3 | 4 |
| 6 | Pushing up on your hands (eg from bathtub or chair) | 0 | 1 | 2 | 3 | 4 |
| 7 | Preparing food (eg. peeling, cutting) | 0 | 1 | 2 | 3 | 4 |
| 8 | Driving | 0 | 1 | 2 | 3 | 4 |
| 9 | Vacuuming, sweeping or raking | 0 | 1 | 2 | 3 | 4 |
| 10 | Dressing | 0 | 1 | 2 | 3 | 4 |
| 11 | Doing up buttons | 0 | 1 | 2 | 3 | 4 |
| 12 | Using tools or appliances | 0 | 1 | 2 | 3 | 4 |
| 13 | Opening doors | 0 | 1 | 2 | 3 | 4 |
| 14 | Cleaning | 0 | 1 | 2 | 3 | 4 |
| 15 | Tying or lacing shoes | 0 | 1 | 2 | 3 | 4 |
| 16 | Sleeping | 0 | 1 | 2 | 3 | 4 |
| 17 | Laundering clothes (eg. washing, ironing, folding) | 0 | 1 | 2 | 3 | 4 |
| 18 | Opening a jar | 0 | 1 | 2 | 3 | 4 |
| 19 | Throwing a ball | 0 | 1 | 2 | 3 | 4 |
| 20 | Carrying a small suitcase with your affected limb | 0 | 1 | 2 | 3 | 4 |
| | **Column Totals:** | | | | | |

**Minimum Level of Detectable Change (90% Confidence): 9 points SCORE: _____/ 80**

**Source**: Stratford et al (2001): Development and initial validation of the upper extremity functional index. Physiotherapy Canada 53 (4): 259-67 .Minimum detectable change (90% confidence): 6 points.

# Disabilities of the Arm, Shoulder and Hand

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

| | NO DIFFICULTY | MILD DIFFICULTY | MODERATE DIFFICULTY | SEVERE DIFFICULTY | UNABLE |
|---|---|---|---|---|---|
| 1. Open a tight or new jar. | 1 | 2 | 3 | 4 | 5 |
| 2. Write. | 1 | 2 | 3 | 4 | 5 |
| 3. Turn a key. | 1 | 2 | 3 | 4 | 5 |
| 4. Prepare a meal. | 1 | 2 | 3 | 4 | 5 |
| 5. Push open a heavy door. | 1 | 2 | 3 | 4 | 5 |
| 6. Place an object on a shelf above your head. | 1 | 2 | 3 | 4 | 5 |
| 7. Do heavy household chores (e.g., wash walls, wash floors). | 1 | 2 | 3 | 4 | 5 |
| 8. Garden or do yard work. | 1 | 2 | 3 | 4 | 5 |
| 9. Make a bed. | 1 | 2 | 3 | 4 | 5 |
| 10. Carry a shopping bag or briefcase. | 1 | 2 | 3 | 4 | 5 |
| 11. Carry a heavy object (over 10 lbs). | 1 | 2 | 3 | 4 | 5 |
| 12. Change a lightbulb overhead. | 1 | 2 | 3 | 4 | 5 |
| 13. Wash or blow dry your hair. | 1 | 2 | 3 | 4 | 5 |
| 14. Wash your back. | 1 | 2 | 3 | 4 | 5 |
| 15. Put on a pullover sweater. | 1 | 2 | 3 | 4 | 5 |
| 16. Use a knife to cut food. | 1 | 2 | 3 | 4 | 5 |
| 17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.). | 1 | 2 | 3 | 4 | 5 |
| 18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.). | 1 | 2 | 3 | 4 | 5 |
| 19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.). | 1 | 2 | 3 | 4 | 5 |
| 20. Manage transportation needs (getting from one place to another). | 1 | 2 | 3 | 4 | 5 |
| 21. Sexual activities. | 1 | 2 | 3 | 4 | 5 |

# Disabilities of the Arm, Shoulder and Hand

| | NOT AT ALL | SLIGHTLY | MODERATELY | QUITE A BIT | EXTREMELY |
|---|---|---|---|---|---|
| 22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)* | 1 | 2 | 3 | 4 | 5 |

| | NOT LIMITED AT ALL | SLIGHTLY LIMITED | MODERATELY LIMITED | VERY LIMITED | UNABLE |
|---|---|---|---|---|---|
| 23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)* | 1 | 2 | 3 | 4 | 5 |

Please rate the severity of the following symptoms in the last week. *(circle number)*

| | NONE | MILD | MODERATE | SEVERE | EXTREME |
|---|---|---|---|---|---|
| 24. Arm, shoulder or hand pain. | 1 | 2 | 3 | 4 | 5 |
| 25. Arm, shoulder or hand pain when you performed any specific activity. | 1 | 2 | 3 | 4 | 5 |
| 26. Tingling (pins and needles) in your arm, shoulder or hand. | 1 | 2 | 3 | 4 | 5 |
| 27. Weakness in your arm, shoulder or hand. | 1 | 2 | 3 | 4 | 5 |
| 28. Stiffness in your arm, shoulder or hand. | 1 | 2 | 3 | 4 | 5 |

| | NO DIFFICULTY | MILD DIFFICULTY | MODERATE DIFFICULTY | SEVERE DIFFICULTY | SO MUCH DIFFICULTY THAT I CAN'T SLEEP |
|---|---|---|---|---|---|
| 29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)* | 1 | 2 | 3 | 4 | 5 |

| | STRONGLY DISAGREE | DISAGREE | NEITHER AGREE NOR DISAGREE | AGREE | STRONGLY AGREE |
|---|---|---|---|---|---|
| 30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)* | 1 | 2 | 3 | 4 | 5 |

**DASH DISABILITY/SYMPTOM SCORE** = $\left[\left(\frac{\text{sum of n responses}}{n}\right) - 1\right] \times 25$, where n is equal to the number of completed responses.

**A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.**

# SF-36 QUESTIONNAIRE

**Name:**_____ **Ref. Dr:**_____ **Date:** _____

**ID#:** _____ **Age:** _____ **Gender: M / F**

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

**GENERAL HEALTH:**
**In general, would you say your health is:**

Excellent Very Good Good Fair Poor

**Compared to one year ago, how would you rate your health in general now?**

Much better now than one year ago
Somewhat better now than one year ago
About the same
Somewhat worse now than one year ago
Much worse than one year ago

**LIMITATIONS OF ACTIVITIES:**
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

**Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.**
Yes, Limited a lot Yes, Limited a Little No, Not Limited at all

**Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Lifting or carrying groceries**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Climbing several flights of stairs**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Climbing one flight of stairs**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Bending, kneeling, or stooping**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Walking more than a mile**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Walking several blocks**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Walking one block**
Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

**Bathing or dressing yourself**

Yes, Limited a Lot | Yes, Limited a Little | No, Not Limited at all

**PHYSICAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

**Cut down the amount of time you spent on work or other activities**

Yes | No

**Accomplished less than you would like**

Yes | No

**Were limited in the kind of work or other activities**

Yes | No

**Had difficulty performing the work or other activities (for example, it took extra effort)**

Yes | No

**EMOTIONAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

**Cut down the amount of time you spent on work or other activities**

Yes | No

**Accomplished less than you would like**

Yes | No

**Didn't do work or other activities as carefully as usual**

Yes | No

**SOCIAL ACTIVITIES:**

**Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all | Slightly | Moderately | Severe | Very Severe

**PAIN:**

**How much bodily pain have you had during the past 4 weeks?**

None | Very Mild | Mild | Moderate | Severe | Very Severe

**During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all | A little bit | Moderately | Quite a bit | Extremely

**ENERGY AND EMOTIONS:**
These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

**Did you feel full of pep?**
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a very nervous person?**
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt so down in the dumps that nothing could cheer you up?**
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt calm and peaceful?**
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you have a lot of energy?**
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt downhearted and blue?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel worn out?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a happy person?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel tired?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**SOCIAL ACTIVITIES:**

**During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

**GENERAL HEALTH:**
**How true or false is each of the following statements for you?**

**I seem to get sick a little easier than other people**

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

**I am as healthy as anybody I know**

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

**I expect my health to get worse**

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

**My health is excellent**

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

OFFICE OF ED & DEAN RESEARCH
Research Ethics Committee
MRIIRS, FARIDABAD
Phone-0129-4198200
Email-dean.research@mriu.edu.in

**15th June, 2023**

***Prof. (Dr.) Moattar Raza Rizvi***
***Supervisor***
***Dean, Faculty of allied health sciences***
***MRIIRS,***
***Faridabad- 121001***

Dear Dr. Rizvi

The MRIIRS Ethics Committee has reviewed your request, for the ethical approval for the research project outlined below.

**"EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON FUNCTIONALITY AND CAPSULAR THICKNESS IN PATIENTS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS.".**

***Ms. Sheena Arora***
***Research Schlor***
***Ph.D Programme, MRIIRS***
***Registration number: 19/Ph.D/009***

The case was discussed in the meeting of Ethical Committee, MRIIRS held on 18/10/2022 vide Online Mode at 10.00 am.

https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZmM2M2E3MGUtZGYwYi00Y2JlLWEwYTItMDNmMGU2Yzk1Yjdh%40thread.v2/0?context=%7b%22Tid%22%3a%22b8b32acb-f158-413f-90bd-ad4479a28acd%22%2c%22Oid%22%3a%2251a86d27-788f-4041-bf2c-152ef5a5f961%22%7d

Further , on examining the research work undertaken vide video presentation mode given by the research scholar , as indicated above , it was resolved that

ethical approval may be granted as the research scholar will obtain consent of subject i.e. type 2 diabetic individuals from Delhi NCR. Also consent letter format / form both English and Hindi has been submitted.

The required documents as asked in the meeting have been submitted today i.e. 15.06.2023 by Prof. (Dr.) Moattar Raza Rizvi, Supervisor Dean, Faculty of allied health sciences MRIIRS. The reason for delay of submission of documents has also been submitted by him.

| | |
|---|---|
| Approval No: | EC/2023-24/035 |
| Approval Date: | 15/06/2023 |
| Expiry Date: | 31/07/2025 |
| Ethics Committee Decision | Approved |

The standard conditions of this approval are:

a) Conduct the project strictly in accordance with the proposal submitted and granted ethics approval. Including any amendments made to the proposal required by the MRIIRS Ethics Committee.
b) Report (email: dean.research@mriu.edu.in) immediately of any complaints or other issues in relation to the research project which may warrant review of the ethical approval of the project.
c) provide a 'progress report' for every year of approval.
d) provide a 'final report' when the project is complete.
e) advise in writing if the project has been discontinued

Please note that failure to comply with the conditions of approval and the "INDIAN COUNCIL OF MEDICAL RESEARCH. 2017. **NATIONAL ETHICAL GUIDELINES**. FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN" may result in withdrawal of approval for the research project.

Sarita 15/6/23

Dr Sarita Sachdeva
ED & Dean Research
MRIIRS

Dean-Research
Manav Rachna International Institute
of Research & Studies
Sector 43, Aravali Hills, Surajkund Road
Faridabad, Haryana 121001

MANAV RACHNA
"vidyanatariksha"

**Dr. O.P. Bhalla Central Library**
**Manav Rachna International Institute of Research and Studies**
*(A deemed-to-be-university under section 3 of UGC Act 1956)*

## SIMILARITY VERIFICATION CERTIFICATE

Title: Efficacy of Mechanical diagnosis & treatment on pain, functionality and capsular thickness in individual with stage 2 diabetic adhesive capsulitis.

Researcher: SHEENA ARORA
Registration Number: 19/PhD/0009

Supervisor: Prof(Dr) Moattar Raza Rizvi
Department: PHYSIOTHERAPY

This is to certify that the above mentioned Short Synopsis/Thesis was scanned for similarity index through Turnitin Software on 29/11/24 ...with submission ID 2281090012 and the similarity index was found to be .....8.....%. The complete report running into .35..Pages, .6158...Word count with File Size.2224...KB is being forwarded to the Research Supervisor/DRC/DRB for review.

Date: 29/11/24

Dr. Rajesh Kumar
University Librarian
Dr. O.P. Bhalla Central Library
Manav Rachna International
Institute of Research & Studies
Faridabad

The complete report of the above Short Synopsis/Thesis has been reviewed and the similarity index is below the accepted norms as per the University Grants Commission (Promotion of Academic Integrity and Prevention of Plagiarism in Higher Educational Institutions) Regulations 2018. The Short Synopsis/Thesis may be considered for further processing

Research Scholar

Research Supervisor 31/1/24

# EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON PAIN, FUNCTIONALITY AND CAPSULAR THICKNESS IN INDIVIDUALS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS

*by* Sheena Arora

**Submission date:** 29-Jan-2024 03:22PM (UTC+0530)
**Submission ID:** 2281090012
**File name:** SS_IN_INDIVIDUALS_WITH_STAGE_2_DIABETIC_ADHESIVE_CAPSULITIS.docx (208.62K)
**Word count:** 6158
**Character count:** 36445

# EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON PAIN, FUNCTIONALITY AND CAPSULAR THICKNESS IN INDIVIDUALS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS

## SHORT SYNOPSIS


*by*

**SHEENA ARORA**

Registration number

19/PhD/009

Under the supervision of

**Prof. (Dr.) Moattar Raza Rizvi**

**Dean, School of Allied Health Sciences**

Joint Supervisor

**Dr. Khyatee**

**Director and Co-Founder**
**Pratyaksh Medical Care LLP, Delhi**
**MANAV RACHNA INTERNATIONAL INSTITUTE OF RESEARCH & STUDIES**
**SECTOR-43, SURAJKUND –DELHI ROAD, FARIDABAD – 121001**


## ABSTRACT


**Background**: Adhesive Capsulitis is a challenging condition marked by pain and limited active and passive range of motion (ROM) of shoulder. Diabetic patients are more prone to develop chronic inflammation and proliferative fibrosis. Physical therapy is the primary form of treatment provided for this condition. Within the realm of shoulder pain assessment and management, the McKenzie Method (MDT) is an area that has received relatively less exploration, particularly in individuals with diabetes.

**Objectives**: This study aims to find out the efficacy of McKenzie (Mechanical Diagnosis and Treatment) method on functionality and capsular thickness in patients with Stage 2 Diabetic Adhesive Capsulitis.

**Methodology:** It will be an RCT with 4 parallel groups (2 intervention and 2 control groups). A total of 24 participants will be collected as per inclusion and exclusion criteria and categorized into groups i.e. 2 groups (Group A1 and A2) with controlled diabetes and 2 groups with uncontrolled diabetes (Group B1 and B2). Group A1 (Controlled Diabetes) will be advised to follow home exercise program with conventional treatment and shall be taken as control for Group A2 (Controlled Diabetes) receiving treatment according to WBDT. Similarly, Group B1 (Uncontrolled Diabetes) will be given conventional treatment for adhesive capsulitis with home exercise and shall be serving as control for B2 (Uncontrolled Diabetes) receiving the WBDT. Outcome variables will be measured at baseline (pre-assessment) and post-treatment at 7 weeks. After completing the treatment the subjects would be given a home exercise program as prophylaxis and they shall be followed up at 3 weeks and 11 weeks and will be again assessed for outcome variables.

**Expected outcome:** WBDT is expected to be valuable tool for diagnosis and treatment for stage 3 diabetic adhesive capsulitis.

**Keywords:** Adhesive capsulitis, Diabetes, Withania Somnifera, Mechanical Diagnosis and Therapy (MDT)

# EFFICACY OF MECHANICAL DIAGNOSIS AND TREATMENT ON PAIN, FUNCTIONALITY AND CAPSULAR THICKNESS IN INDIVIDUALS WITH STAGE 2 DIABETIC ADHESIVE CAPSULITIS

ORIGINALITY REPORT

Rajesh Kumar 29/1/24

University Librarian
Dr. O.P. Bhalla Central Library
Manav Rachna International
Institute of Research & Studies
Faridabad

| 8% | 7% | 7% | 2% |
|---|---|---|---|
| SIMILARITY INDEX | INTERNET SOURCES | PUBLICATIONS | STUDENT PAPERS |

Excluding matches less than 14 words

PRIMARY SOURCES

| | | |
|---|---|---|
| 1 | Submitted to Manav Rachna International University<br>Student Paper | 1% |
| 2 | www.jospt.org<br>Internet Source | 1% |
| 3 | academic.oup.com<br>Internet Source | 1% |
| 4 | www.mdpi.com<br>Internet Source | 1% |
| 5 | www.worldwidejournals.com<br>Internet Source | 1% |
| 6 | "ICSES e-Poster Presentations", JSES International, 2023<br>Publication | 1% |
| 7 | www.kheljournal.com<br>Internet Source | 1% |
| 8 | journal.parker.edu<br>Internet Source | <1% |

| | | |
|---|---|---|
| 9 | ojshostng.com<br>Internet Source | <1 % |
| 10 | www.rbf-bjpt.org.br<br>Internet Source | <1 % |
| 11 | Submitted to Arcadia University<br>Student Paper | <1 % |
| 12 | Jong Geol Do, Jin Tae Hwang, Kyung Jae Yoon, Yong-Taek Lee. "Correlation of Ultrasound Findings With Clinical Stages and Impairment in Adhesive Capsulitis of the Shoulder", Orthopaedic Journal of Sports Medicine, 2021<br>Publication | <1 % |
| 13 | Milena Cerny, Patrick Omoumi, Ahmed Larbi, Daniel Manicourt et al. "CT arthrography of adhesive capsulitis of the shoulder: Are MR signs applicable?", European Journal of Radiology Open, 2017<br>Publication | <1 % |
| 14 | Submitted to Cardiff University<br>Student Paper | <1 % |
| 15 | Shoulder Stiffness, 2015.<br>Publication | <1 % |

Exclude quotes On

Exclude bibliography On

Exclude matches < 14 words